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14. ABSTRACT

Site personnel were hired at all sites and are in the field. New site PIs are in place at BAMC and Ft Stewart. The BRAC transition to WRNMMC substantially slowed site progress with enrollment and IRB matters. Data collection has begun at all 3 sites. Extensive site development and recruitment has increased family enrollment to a total of 33 families.

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INTRODUCTION:

This investigation focuses on measuring the impact of parental combat injury on military children and families. The study is a longitudinal design comparing families of combat-injured service members (CI group) and non-injured service members (NI group) across a 12-month time-frame. The CI group will be comprised of 200 injured service members and their spouses with at least one child under the age of 18-years-old recruited from Walter Reed National Military Medical Center (WRNMMC) and Brooke Army Medical Center (BAMC) within the first two years of initial hospitalization. The NI group will be comprised of 200 active duty non-injured combat veterans (matched with CI participants for combat experience and relevant demographic factors) and their spouses with at least one child under the age of 18-years-old recruited from Ft. Stewart, GA (FSGA), within two years of returning from deployment. Families will be assessed using self-report questionnaires and, for the CI Group, record review of a semi-structured interview currently used at clinical sites. Consenting parents and assenting children ages 6 to 17 years will complete questionnaires assessing the following domains: parental trauma exposure history, symptoms, and function; child traumatic exposure history, symptoms and function; parenting behaviors; and family functioning. Follow-up assessments of parental symptoms and functioning, child symptoms and functioning, parenting behaviors, and family functioning will be completed 6 and 12 months after the initial assessment. For families who are not available to complete in-person assessment at 6 and/or 12 months, assessment will be conducted by telephone and measures will be administered verbally or assessment will be conducted online. Families will also be briefly contacted at 3-months and 9-months after baseline to check-in and inquire whether they are in need of additional resources.

BODY:

Below is a summary of the major activities undertaken by project team members during the last 12 months organized by the timeline in the Schedule of Work (SOW):

1. **Program Personnel Recruitment and Hiring**: Complete.

   WRNMMC: Ms. Mona Mendelson, LCSW, the Research Clinician at WRNMMC continues recruitment and data collection; details of progress at WRNMMC follow below. Ms. Heidi Shull, LPCA, has also been hired as a full-time Research Clinician at WRNMMC. Ms. Shull began work on September 1, 2011. Ms. Mendelson and Ms. Shull will be working collaboratively on this project, as well as another CDMRP grant to maximize recruitment and to build efficiency in project completion.

   BAMC: Given the challenges in recruitment at BAMC, we changed criteria for an independently privileged, full-time research clinician to fill the vacancy. As a result, Dr. Yolanda Rodriguez-Escobar, the Research Clinician at BAMC, left the project. We focused on finding a full-time Clinician to facilitate recruitment and subject data collection flow. Ms. Cheryl Camarillo, LCSW, has been hired as the full-time Research Clinician at BAMC. Ms. Camarillo began work on September 1, 2011. We are also interviewing a second site clinician at BAMC with the goal of boosting our recruitment efforts.

   FSGA: We have had great difficulty filling the position at FSGA which has substantially delayed our projected recruitment and enrollment goals. In the past year, a candidate accepted the Research Clinician position, but later rescinded her acceptance. After a lengthy candidate search, Ms. Dana Frasier, LPC, was hired as the full-time Research Clinician at FSGA. She began work on December 1, 2011.

2. **Staff and Clinician Training**: Complete.

   Research Clinicians (RCs) at all 3 sites have been added to the IRB protocol, are fully trained, and are in the field recruiting. First, all Research Clinicians have completed the necessary CITI training and HJF orientations. With new hires and the change in inclusion criteria approved by the funder and IRB (i.e., service members with children under 18 years old and within 2 years of hospitalization or return from deployment), a training manual "Addressing the Needs of Children and Families of Combat Injured: Recruitment, Enrollment, and Data Collection Manual" was developed. As part of the project orientation and training, Research Clinicians received project materials including relevant background literature, project protocol, training manual, consent forms, questionnaires, and project advertisements in addition to the participant tracking databases. RCs reviewed materials at their local sites; were trained in-person at CSTS on all project logistics; and BAMC and FSGA RCs

traveled to train at WRNMMC with WRNMMC RCs to practice provider and participant interaction. RCs are now in the field at their local sites actively engaging the community in outreach to obtain referrals and enrolling participants.

3. **Organization and Preparation**: In Process.

Organizational Systems. Several organization systems have been enacted in preparation for launch at all sites and to monitor activities after launch.

A uniform project-wide system was established to track the recruitment process and best capture universe of participants (i.e., CI- combat injured service members with children; NI- service members returned from deployment with children). At each site, RCs identify all encounters with families: where (i.e., what department/provider/event) and when the RC met the family, if the referral was obtained, why referrals were not obtained, when the RC initiated recruitment, enrollment outcome, and why family is not enrolled. This system has allowed us to: 1) estimate the current population of families from available departments, 2) determine most effective referral sources, 3) track timelines for referral and enrollment processes, 4) identify reasons for families not enrolling in the study, and 5) for each site, problem-solve at specific stages accordingly. As anticipated, there are as much between-site differences as within-project similarity.

Additionally, we have established a project-wide system for tracking enrolled participant interviews: when each interview and check-in is scheduled and then completed; and if there were concerns (e.g., anxiety) or services the participant needed (e.g., child care) and then where the participant was referred (e.g., Behavioral Health Clinic, Army Community Services).

To assist in project management, problem-solving with provider outreach, and case management with data collection, a Weekly Activity Report for RCs was created. The Weekly Activity Report tracks all major project activities: administrative tasks, awareness and outreach (tasks to prompt referrals of participants from providers or self-referral), recruitment (enrolling families), data collection and check-in, and training and supervision. RCs submit reports each week.

Recruitment Materials and Strategies. We have worked to generate new and maximize all recruitment efforts to increase project awareness within the community and boost provider- and self-referrals.

First, we have sought command support and connected directly to providers establishing presence and community awareness of the study. Through command and director level approval, we are building entre into several clinics and groups. At each meeting providers are given project materials (e.g., summary memo, project presentation, project protocol, recruitment flyer, CSTS materials) for clinic reference about the study and visual reminder of the collaboration we are establishing with them. This has been a critical step as we launched at FSGA, and "relaunched" at BAMC and WRNMMC after the Base Realignment and Closure (BRAC).

Second, we reinforce our presence through participation in community events for families (e.g., Family Health Fair, events during Month of the Military Child) by providing informational tables about the study and activities for children. These efforts have yielded self-referrals, built trust with families by demonstrating our commitment to families as community members rather than research specimen, reinforced relationships with providers, built relationships with new providers who are interested in the study, and promoted positive awareness of the study throughout the military community. As we see the same families and providers at multiple events and clinics, our credibility and validity has grown and interest in the study has increased.

Third, we are using multiple mechanisms to facilitate provider and self-referral. For providers, we have created reminder cards of the provider referral process explicitly outlining the steps taken to refer a participant to the RC. Providers now have the option to call or email the RC to give a referral. All providers in a clinic or group are given the reminder cards; RCs verbally reference the cards to facilitate referrals when stopping by a provider location. Additionally, we created a "Sign-up Box" for both provider and self-referrals. This is similar to a suggestion box, but serves as a referral mechanism. There are cards to collect participant name and contact information, which are then placed in a locked box. Providers have responded very positively to the "Sign-up Boxes". They now use the sign-up cards in the exam rooms to collect referral information and can have

participants sign-up immediately, minimizing provider burden while maximizing retention of participant and relay of information to RCs.

4. **Site Approval and Planning**: In Process.

Overall: While the project has been on-going for a few years, the prolonged process for site and IRB approvals; BRAC at BAMC and recently at WRNMMC; and securing site PIs and RCs have substantially delayed the projected launch and enrollment of participants at study sites. However, during the past year, we have made notable progress in each of these site development areas enabling project launch at all sites (including "relaunch" at WRNMMC and BAMC) and built the foundation for projected enrollment success.

Additionally, we received funder and IRB approval to modify the inclusion criteria to include families with children as young as infants up to age 18 and families up to 2 years since hospitalization or return from deployment. This was necessary to match the change in demographics of the current fighting force: young service members with several young children under the age of 3 years. To reflect the inclusion of infants and toddlers in the study, we added measures assessing the social and emotional competence of infants and toddlers and measures assessing parenting competence relevant to parenting young children.

It was also difficult to access injured patients during the acute phases of recovery (i.e., 6 months after hospitalization). Expanding the criteria to 2 years includes a larger population of families in outpatient care and, at FSGA, families at various stages of reintegration. The expansion of inclusion criteria will result in a more representative sample of injured and deployed service member populations and their families, and allows us to more effectively recruit families into the study.

Lastly, we have received IRB approval to interview children via various media (e.g. using the internet or telephone) to increase child participation. At WRNMMC, we found that children did not visit their parent in hospital preventing enrollment in the study.

WRNMMC: This past year the BRAC between WRAMC and NNMC resulted in a transition of our study site to WRNMMC. BRAC consolidation between WRAMC and NNMC and the need to establish IRB site approval at the new WRNNMC closed recruitment during the move. WRNMMC enrollment was placed on hold during the WRAMC BRAC move to WRNMMC on 8/20/11; enrollment resumed 10/11/11. The BRAC impeded access to subjects while patients and departments moved, and departments integrated. Accessing subjects and providers for referrals is tenuous. We have fervently continued to request referrals from departments and providers who we previously established relationships with at WRAMC (e.g., inpatient Behavioral Health services).

Although WRAMC was previously a functioning site for enrollment, WRNMMC required a "relaunch". We are re-establishing the study and building site partnerships needed to access the patient population; a strong infrastructure at each site is needed for project success. At WRNMMC, there is new command, command structure, department structure, provider service, patient flow, and family services. RCs and project leadership are engaging in extensive outreach to educate important referral sources about the study and procedures and to develop connections with key site staff who work with families (e.g., Pediatrics, Fleet and Family Services, Family Care Club). We are also connecting with providers who serve injured service members (e.g., Physical Therapy, Occupational Therapy, Traumatic Brain Injury Clinic, Warrior Clinic). These providers are important collaborators for accessing the study population. For instance, PT serves both inpatient and outpatient amputees; we are working with the providers to get an estimate of their current patients who meet the expanded inclusion criteria. The Warrior Clinic serves all service members attached to a Warrior Transition Unit or service members requiring more than 6 months treatment; currently, an estimated 40 service members could meet the expanded inclusion criteria. Our intensive site development and recruitment efforts with providers are laying the foundation for successful enrollment.

During the BRAC transition, WRNMMC requested we establish an IAIR agreement to defer all IRB action to the USUHS IRB. We have submitted the IAIR for WRNMMC to defer IRB approval to USUHS. This will increase subject flow because we will not have to wait for additional WRNMMC IRB approvals. However, we cannot recruit according to the expanded inclusion criteria until the IAIR is approved. As previously mentioned, this will

substantially facilitate recruitment efforts. In addition to the outpatient clinics with eligible families, our current referral sources have referred families who would meet eligibility criteria. RCs have spoken with 6 families who have indicated interest in participating and eagerly await the new consent forms allowing them to do so. We await approval from the USUHS IRB who is coordinating the WRNMMC IRB. The new WRNMMC IRB is backlogged due to the BRAC; we will continue to remain actively engaged with the IRB to facilitate rapid approval.

BAMC: All IRB and HRPO approvals are in place. Due to changes in responsibilities of Dr. Alan Maiers, a new site PI for BAMC was identified on the USUHS IRB protocol, Dr. Terry Arata-Maiers, in July 2011. With the change in site PI, new RC, completion of BRAC, recruitment was on hold from July 2011 – December 2011. Dr. Arata-Maiers is actively engaged in the project, promoting the study with command and clinical leadership, and supporting the new RC.

Similar to WRNMMC, we "re-launched" at BAMC. The changes in staff, BRAC, and study eligibility criteria provided an opportunity to re-establish the study within the new BAMC setting as providers were settling from the BRAC moves. Drs. Cozza and Holmes made a site visit to BAMC on 13 and 14 SEP 2011 to assess progress and to support greater awareness and engagement around the project. Through the coordination of the BAMC Site PI, we reestablished connections with stakeholders, command, and service providers (e.g., Center for the Intrepid, Warrior Transition Brigade, Soldier and Family Assistance Center (SFAC), Nurse Case Managers) and forged new relationships with groups serving families (e.g., Warrior and Family Support Center (WFSC), Fisher House). With a new research team and infrastructure on site, the RC has created a high level of project awareness in the BAMC community, promoting participant self-referral into the project, and encouraging provider support. We are finding at BAMC that the combat-injured population is a tight-knit community, families are participating in many research studies, and providers are also requested to support several other research studies. Our continued efforts to align with the community, both families and providers, are essential components for recruitment and we are building successful foundations to this end.

FSGA: All IRB and HRPO approvals are in place. Due to the change of assignment of Dr. Janice Tanner, a new site PI for FSGA was identified and added to the UUSHS IRB protocol, Dr. Erin Field, in June 2011. Dr. Field is supportive and enthusiastic for completing the study. As previously mentioned, the site RC was hired and began work December 2011. Drs. Cozza and Holmes made a site visit to FSGA on 30 AUG 2011 to assess progress, build greater awareness and engagement around the project, and secure the recruitment infrastructure, (e.g., we received WINN hospital command support). We established connections with FSGA service providers, command, and community members. Dr. Holmes and RC, Ms. Frasier, made a series of briefs with service providers including Behavioral Health, Family Practice, Pediatrics, Army Community Services (ACS), and Family Readiness and Support Assistance leadership who see families on regular basis. All groups echoed the importance of the study and high volume of families who should study criteria (e.g., Family Practice sees 1000 families per week). Despite the strong support from providers, but we were cautioned of the hesitation families tend to have participating in research studies and that it will take a building a trust in the community before we see the resulting enrollment. The site has numerous families who qualify for participation (i.e, service members with children and have recently returned from deployment, and 2 units expected to return this summer). The robust presence of the RC at post events for families at the Px, Child Development Centers, and ACS events and continued relationship building with providers has solidified provider buy-in with the study. This site foundation has led to increased self-referral and we are confident it will lead to further provider- and self-referral for participant enrollment success.

5. **Finalize Plans:** In Process.

Overall: With all sites on line, we maintain connection to RCs through weekly team calls with all RCs, project coordinator, and RAs. In addition to individual site problem-solving and data collection case management, the call facilitates team building. RCs can support each other and further success at other sites with tips on "what works best". We also continue to have cross-site monthly project calls with the research team: all site PIs, RCs, project coordinator, and project PI.

WRNMMC: After the move to WRNMMC, office space was secured in the Deployment Health Clinical Center (DHCC), a supportive hospital partner. We have secured part-time interview space in DHCC and in Child and Adolescent Psychiatry Services. We continue to connect with the community and explore opportunities for a permanent interview space. However, interviews are conducted when and where families are available (e.g., hospital room, hotel room), when privacy is ensured.

BAMC: Office space was secured through the site PI at the Warrior Resilience Program office. The office affords desk space and secure file storage. Interview space is available on an as-needed basis through provider partners at the SFAC and WFSC. We continue to connect with the community and explore opportunities for permanent interview space. However, interviews are conducted when and where families are available (e.g., hospital room, hotel room), when privacy is ensured.

FSGA: A private office space was secured through the community partner, ACS. The locked office has desk space and secure file storage. It also serves as a space for conducting interviews with a table and chairs. The office is located in a "neutral" building not associated with behavioral health reassuring participants that the study not a psychological assessment and is not a military service. Moreover, the office shares a suite with the Military Family Life Consultants (MFLCs), short-term contract counselors who families may see for services, but the visits are not documented on the family's military or health record; we are likened to a confidential and secure haven for sharing their story. We also have interview space on an as-needed basis at the Behavioral Health Soldier Resiliency Clinic and whenever space is available at the Pediatrics Clinic. Interviews are also conducted when and where families are available (e.g., family home), when privacy is ensured.

6. **Participant Enrollment and Data Collection**: In Process.

We have enrolled 33 families, cumulatively, across all three sites.

WRNMMC: Data collection continues at WRNMMC. Twenty two families have been enrolled to date, 11 in the past year. As mentioned, several families have been identified who would be eligible for the study under the extended inclusion criteria, but we cannot recruitment them until the IAIR is approved.

Follow-up data collection continues for enrolled participants. We are successful in maintaining contact and achieving the follow-up interviews with notable exceptions:

One participant (service member receiving treatment at WRNMMC) died due to the severe nature of his combat injuries and subsequent treatments. His death was not related to participation in the current study. Participant death, specifically the combat-injured service member, is a rare but possible scenario of the population for the current study. The spouse of the deceased service member is also participating and we have connected her with bereavement services.

One participant (service member receiving treatment at WRNMMC) voluntarily withdrew from the study at the last assessment wave (12-month follow-up) after completing the baseline interview. The service member was greatly dissatisfied with the BRAC move to WRNMMC and subsequent care he received at WRNMMC, frustrated with his son's schooling and the lack advocacy in the school system, and did not want to give his time for any more interviews. Many attempts were made for several months to complete a follow-up interview. His spouse was also participating, but she completed all 3 interviews. The service member supported his wife's participation but found his participation to be too overwhelming. However, he did find openly talking and expressing all his stress and frustration to be helpful. When he finished explaining his reasons for withdrawing from the study, he admitted that he could have completed the interview by this time (45minutes), but remained resolute for terminating his participation. We find this case to support the aim of the study and need for following families for a year: combat-injury is not an insular event resolved immediately. The long-term effects have substantial impacts on the family and later stressors can have additive or compounding influences on individuals' adjustment.

To date, 11 families have completed the study (i.e., 12-month follow-up interview).

BAMC: With the change in site PI, new RC, and completion of BRAC, recruitment was on hold from July 2011 – December 2011. Data collection was re-launched on 12/1/11. Five families have enrolled to date. As we are still developing relationships with providers and the community, we are encouraged that 33 families have been referred. Of these, 11 were not eligible (due to nature of injury or family structure), 2 refused participation, and 11 are still being contacted for recruitment. We find that these families are under many stresses and the recruitment process can take several weeks, but when times can be arranged, families are willing to participate. Our goal is to continue to identify provider referral sources with eligible families and strategize techniques for enrolling distressed families.

FSGA: Recruitment commenced 12/22/11. Six families have enrolled to date. We are very optimistic about the increased enrollment at FSGA because we have 67 referred families to date. Of these 37 were not eligible, 4 refused participation, and 20 are still being contacted for recruitment. It is most notable that the number of referrals increases each week and the refusal rate is very low. Our goal is to continue outreach for referrals and press for scheduling enrollment interviews.

7. **Monitor Data Collection**: In Process.

   With the launch of all 3 sites, we monitored our progress and adapted to the needs and structure of the sites to best facilitate site development, recruitment, and maintaining contact with participants. In the past 2 months, we have adapted our tracking systems to streamline this process to ensure we are capturing all necessary research data while minimizing burden on RCs.

   As previously mentioned, we adapted the questionnaires due to the expansion in inclusion criteria. We have also streamlined the organizational structure of the collection process. With initiation of data collection, Dr. Holmes began quarterly site visits for retrieval of hard copy questionnaires to deposit in secure CSTS storage. The site visits also allow for on-site problem-solving and maintenance of systematic data collection processes.

   Lastly, we are making final edits to the online data collection system, PsychData. The modifications of questionnaires and inclusion criteria necessitated changes to the online system. The changes are being finalized and we anticipate launch within the month.

8. **Problem Areas**:
   First, the delays due IRB approvals, BRAC transitions, and changes in site PI and personnel substantially postponed project launch at FSGA and required the relaunch at WRNMMC and BAMC (as described above). These delays slowed our anticipated enrollment rate. However, our intensive site development and recruitment efforts at all sites will increase enrollment.

   Second, the IRB delays at WRNMMC for establishing the IAIR agreement with USUHS are suppressing expanded enrollment. These additional families have been identified and will be eligible for recruitment once the IAIR agreement is in place. Continued delays in WRNMMC deferral to USU IRB will result in reduced enrollment numbers and slower recruitment into the protocol. We will continue to remain actively engaged with the IRB to facilitate rapid approval.

   Third, fewer service members are being severely injured, which will reduce our recruitment pool. The number of new inpatient service members who are eligible is limited. We must focus efforts on locating families receiving outpatient services, which makes the expanded criteria within 2 years of hospitalization and continued site development essential for recruitment success.

KEY RESEARCH ACCOMPLISHMENTS:

To date, we enrolled 33 families cumulatively. Compared to last year, we have increased enrollment by threefold. This achievement is due largely to: 1) relaunch/launch of all 3 sites, 2) extensive and intense site development campaigns, 3) full-time RCs recruiting families, 4) extended participant inclusion criteria, 5) high numbers of referred families, and 6)

low participant refusal rate upon recruitment. Both provider and family interest in the study is encouraging allowing us to expand further into the community. We now have families referring other families into the study for enrollment. Although the establishment within the sites is a building process, we are seeing the progress and positive outcomes.

REPORTABLE OUTCOMES:

We continue to increase our enrollment numbers, follow-up data collection, and have some families who completed the study. At injured and non-injured sites alike, parents and children report distress during the interviews and with the RCs in conversations. Parents have been very protective of their children which has limited direct child interview; we are problem-solving and using various techniques, such as motivational interviewing, to encourage child participation. However, nearly all participants have indicated that the interviews have helped them and they enjoyed talking with someone.

CONCLUSION:

With all 3 sites fully operational and continued progress being made to support the site development, recruitment, and data collection efforts, our enrollment success will persist. The institutional delays of IRB have, for the most part, been resolved. The remaining IAIR matter at WRNMMC is being addressed and once the deferral agreement is in place, enrollment at the site will greatly increase. We have created collaborative relationships with many providers and are building trust with families within the injured community at WRNMMC and BAMC and on post at FSGA. Through these relationships, recruitment materials designed to facilitate referral while minimizing burden on providers and families (e.g., sign-up cards), and increased presence at the sites, we are achieving project goals.

REFERENCES:

No references were cited in this annual report.

APPENDICES:

None supplied.